U.S. DEPARTMENT OF ENERGY OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

OFFICE OF QUALITY ASSURANCE

AUDIT REPORT LANL-ARC-02-02

OF THE

LOS ALAMOS, NEW MEXICO

NOVEMBER 13 – 15, 2001

Prepared by:		Date:		
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Approved by	:	Date:		
FF	Ram Murthy			
	Acting Director			
	Office of Quality Assurance			

1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit LANL-ARC-02-02, the audit team determined that the Los Alamos National Laboratory (LANL) located in Los Alamos, New Mexico is satisfactorily and effectively implementing the applicable portions of the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM) QA Program in accordance with DOE/RW-0333P, Revision 10, *Quality Assurance Requirements and Description* (QARD), OCRWM program procedures and LANL implementing procedures.

The audit team identified six conditions adverse to quality that resulted in the issuance of two Deficiency Reports (DR) described in paragraph 5.5.2, one Deficiency Identification and Referral (DIR) described in paragraph 5.5.3, and three conditions adverse to quality were corrected during the audit (CDA) and prior to the post-audit meeting as described in paragraph 5.5.4.

DR BSC-02-D-034 - The prerequisite section for TWP-NBS-HS-000001, Rev, 01, identifies LANL procedure YMP-QP-S5.01 as the QARD Supplement V implementing document for LANL work. There is no objective evidence of an evaluation being performed for this LANL procedure as required by AP-SV.1Q, Revision 0, ICN 2, *Control of the Electronic Management of Information*.

DR BSC-02-D-035 - This DR identifies that the technical work plan does not adequately address individual activities performed and technical products produced by LANL for the Busted Butte investigation as required by AP-2.21Q, Revision 1, BSCN 1, Quality Determination and Planning for Scientific, Engineering, and Regulatory Compliance Activities.

DIR-02-02 - Additional examples of conditions adverse to quality relating to DR BSC-02-D-009 were found. This DIR addresses the fact that Data Tracking Number submittals classified as "final" do not show evidence of reviews as required by AP-2.14Q, Revision 2, *Review of Technical Products and Data*.

In addition, the effectiveness of corrective actions related to three previously closed DRs were evaluated with satisfactory results. The details are described in paragraph 5.5.5.

There were no recommendations initiated as a result of the audit.

2.0 SCOPE

Auditors representing the DOE's Office of Quality Assurance (OQA) conducted a compliance audit to evaluate LANL's implementation of the OCRWM QA Program as described in the QARD and applicable implementing procedures at the LANL facilities. In addition, an individual representing the Clark County, Nevada Department of Comprehensive Planning, observed the audit.

The audit team, through interviews of cognizant personnel, reviews of documentation, and evaluation of procedures, assessed implementation, adequacy, and effectiveness of LANL's implementation of the QA Program.

The audit team also reviewed the status of recently closed OCRWM deficiency documents generated during previous OQA audits and surveillances of LANL to determine the effectiveness of completed corrective actions.

In accordance with the approved audit plan, the following QA program sections were evaluated:

QA PROGRAM SECTIONS

1.0	Organization
2.0	Quality Assurance Program
5.0	Implementing Documents
6.0	Document Control
7.0	Control of Purchased Items and Services
12.0	Control of Measuring and Test Equipment
15.0	Nonconformances
16.0	Corrective Action
17.0	Quality Assurance Records
Supplement I	Software
Supplement II	Sample Control
Supplement III	Scientific Investigation
Supplement V	Control of the Electronic Management of Data
Appendix C	Monitored Geologic Repository (limited to Purchased Items and Expert Elicitation)

The following QA program sections were not evaluated, as LANL is currently not implementing them:

Design Control
Procurement Document Control
Identification and Control of Items
Control of Special Processes
Inspection
Test Control
Handling, Storage, and Shipping
Inspection, Test, and Operating Status
Audits
Field Surveying
High-Level Waste Form Production
Storage and Transportation

3.0 AUDIT TEAM AND OBSERVERS

The following is a list of audit team members and their assigned areas of responsibility:

Name/Title/Organization

James V. Voigt, Audit Team Leader, Navarro Quality Services (NQS) Christian M. Palay, Auditor, NQS F. Harvey Dove, Auditor, NQS Patrick V. Auer, Auditor, NQS

Audit Observer Name

Engelbrecht von Tiesenhausen

QA Program Sections

1.0, 2.0, 12.0, 16.0, and 17.0

Supplements III and V 15.0, 17.0, Supplements I and III 5.0, 6.0, 7.0, 17.0, Supplement II and Appendix C

Organization

Clark County, Nevada Department of Comprehensive Planning

4.0 AUDIT TEAM MEETINGS AND PERSONNEL CONTACTED

The pre-audit meeting was held at LANL's offices in Los Alamos, New Mexico on November 13, 2001. Daily debriefings were held to apprise LANL management and staff of the progress of the audit and any conditions adverse to quality. The audit was concluded with a post-audit meeting held on November 15, 2001 at LANL's Los Alamos, New Mexico offices.

Personnel contacted during the audit, including those who attended the pre- and post-audit meetings, are listed in Attachment 1, "Personnel Contacted During the Audit."

5.0 SUMMARY OF AUDIT RESULTS

5.1 **Program Effectiveness**

The audit team concluded that, overall LANL's implementation of the QA program is adequate and is effectively implemented with the exceptions noted in Section 5.5. The results for each QA program section evaluated are contained in Attachment 2, "Summary Table of Audit Results."

5.2 Stop Work or Immediate Corrective Actions Taken

There were no Stop Work Orders or immediate corrective actions initiated as a result of the audit.

5.3 QA Program Implementation

Attachment 2, "Summary Table of Audit Results," provides results for each QA program section audited. The details of the audit, including the objective evidence reviewed, are documented in the audit checklist. The checklist is maintained as a QA record.

5.4 Technical Audit Activities

There were no technical activities evaluated during this audit.

5.5 Summary of Conditions Adverse to Quality

The audit team identified a total of six conditions adverse to quality during the audit from which two DRs and one DIR have been issued. Three conditions adverse to quality were identified and CDA prior to the post-audit meeting. Details of the DRs are provided in Section 5.5.2, the DIR in Section 5.5.3, and CDAs in Section 5.5.4.

5.5.1 Corrective Action Request

None.

5.5.2 <u>Deficiency Reports</u>

DR BSC-02-D-34

No objective evidence was provided to demonstrate that a QARD Supplement V evaluation had been performed on a LANL procedure (LANL-YMP-QP-S5.01) for LANL electronic data management. In Technical Work Plan, TWP-NBS-HS-000001, the prerequisite section does identify the LANL procedure, LANL-YMP-QP-S5.01, as the implementing document for the management of electronic information for LANL work scope activities defined in Work Package 4201224UMH.

DR BSC-02-D-035

The scope of work documented in Section 1 of TWP-NBS-HS-000001, Revision 01, does not reflect the work activities being implemented at LANL. Specifically, the technical work plan fails to acknowledge LANL as a key organization supporting Unsaturated Zone Flow and Transport work documented in Table 1.1 and Section 1.8 of Work Package 4201224UMH, *Busted Butte Investigation*. This deficient condition is in violation of AP-2.21Q, Attachment 4, Section 1 entitled "Work Scope," which states in part "Also include which organization is responsible for the overall effort and which organizations support the work." The work plan does not address the individual activities performed and technical products produced by LANL for the Busted Butte Investigation.

5.5.3 Deficiency Identification and Referral

DIR-02-02: Based on objective evidence reviewed, additional examples were found of conditions adverse to quality for DR BSC-02-D-009. Data Tracking Number submittals classified as 'final' do not show evidence of reviews as required by AP-2.14Q.

5.5.4 <u>Deficiencies Corrected During the Audit (CDA)</u>

- 1. Recently opened Scientific Notebook (SN), SN-LANL-SCI-261-V1, did not have an active "Table of Contents"; a Table of Contents was verified to be CDA. This condition was isolated to this SN of those sampled.
- 2. The SN Register contained erroneous information regarding SN-LANL-SCI-241-V1. This condition was isolated to this SN of those sampled. The register was updated and verified to be CDA.
- 3. Two LANL staff were not identified for read only training to a recently revised internal LANL procedure. The names were added to the training database and training acknowledgement forms distributed prior to completion of the audit. This was verified as CDA.

5.5.5 Follow-up of Previously Issued Deficiency Documents

Three deficiency documents were evaluated for effectiveness of corrective actions.

LVMO-01-D-013 – Effective corrective actions were confirmed by verifying that the correct version of controlled documents were either in use by controlled copy or by on-line printed version.

LANL-01-D-006 - LANL control of Measuring and Test Equipment as required by Administrative Procedure AP-12.1Q, Revision 0, ICN 1, *Control of Measuring and Test Equipment and Calibration Standards* was confirmed by examining current activities and verifying effective implementation.

LANL-01-D-117 - Effective corrective actions were confirmed by verifying that training for specific work activities, such as initiating a Scientific Notebook, were competed prior to the performance of that activity.

6.0 **RECOMMENDATIONS**

No recommendations were documented for LANL management consideration.

7.0 List of Attachments

Attachment 1 - PERSONNEL CONTACTED DURING THE AUDIT

Attachment 2 - SUMMARY TABLE OF AUDIT RESULTS

Attachment 3 - ACRONYMS/ABBREVIATIONS

ATTACHMENT I

PERSONNEL CONTACTED DURING THE AUDIT

		Pre- Audit	Contacted During	Post- Audit
Name	Organization/Title	Meeting	Audit	Meeting
Buenviaje, Paul	BSC, LANL On-Site Representative	X	110010	X
Counce, Dale	LANL, Technical Staff		X	
Ding, Mei	LANL, Technical Staff	X		
Dixon, Paul	LANL, Laboratory Lead	X		
Gaither, Kathy	SNL, Technical Staff Disruptive Events	X		
Gray, Elizabeth LANL, Records/Training/Document Control Consultant			X	
Gundlack, Brad	LANL, Software Configuration Lead	X	X	
Hudy, Edy	BSC, Document Control		X	
Levy, Schön	LANL, Tech Coordinator		X	
Martinez, Cleoves	LANL, Engineering Assurance Mgr.	X	X	X
Mason, Jeffery	BSC, Software Configuration		X	
	Management			
McGoldrick, John	BSC, Procurement Staff		X	
McGraw, Maureen	LANL, Technical Staff		X	
Persoff, Peter	LBNL, Data Verification		X	
Reimus, Paul	LANL, Technical Staff		X	
Roback, Robert	LANL, Technical Staff Disruptive Events		X	
Scism, C.	LANL, Laboratory Technician		X	
Snow, Marjorie	LANL, Technical Staff - Mineralogy		X	
Serrano, Ramon	LANL, Technical Staff Calibration Lab		X	
Stone, Dan	LANL, Data Coordinator		X	
Tseng, Peng-Hsiang	LANL, Principle Investigator		X	
Turin, H. Jake	LANL, Technical Staff		X	
Valentine, Greg	LANL, Technical Activity Lead		X	
Young, James	LANL, QA Specialist M&TE, Data	X	X	X
Warnock, Maryam	LANL, QA Specialist for Records, Training, and Document Control	X	X	
Wolfsberg, Laura	LANL, Principle Investigator		X	

ATTACHMENT 2

SUMMARY OF AUDIT RESULTS

QA Section/ Activities	Document Review	Reference to Checklist Pages	Deficiencies /DIR	CDA	REC	Program Adequacy	Procedure Compliance	Over- all
1.0	LANL-YMP-QP-01.4, R7 LANL-YMP-QP-01.3, R6	Pgs. 1-2 Pgs. 3-4				SAT SAT	SAT NI	SAT
2.0	LANL-YMP-QP-02.12, R3 AP-2.1Q, R2, ICN 0 AP-2.2Q, R1, ICN 0	Pg. 5-6 Pgs. 7-8 Pgs. 9-10		CDA #3		SAT SAT SAT	NI UNSAT SAT	SAT
5.0	AP-5.2Q, R0, ICN 2	Pgs. 11-13				NI	NI	NI
6.0	LANL-YMP-QP-06.2, R9 LANL-YMP-QP-06.3, R9 AP-6.1Q, R6, ECN1 LANL-YMP-QP-06.1, R9 AP-6.28Q, R0, BSCN1,	Pgs. 14-15 Pgs. 16-17 Pgs. 18-21 Pgs. 22-26 Pgs. 27-30				SAT SAT SAT SAT SAT	SAT SAT NI SAT NI	SAT
7.0	AP-7.7Q, R0, ICN2	Pgs. 31-34				SAT	SAT	SAT
12.0	AP-12.1Q, R0, ICN1	Pgs. 35-41				SAT	SAT	SAT
15.0	AP-15.2Q, R0, ICN 1	Pgs. 42-43				SAT	NI	SAT
16.0	AP-16.1Q, R4, ICN1	Pg. 44				SAT	NI	SAT
17.0	AP-17.1Q, R2, ICN1	Pgs. 45-46				SAT	SAT	SAT
SUPP I	AP-SI.1Q, R3, ICN2,ECN1	Pgs. 47-50				SAT	SAT	SAT
SUPP II	LANL-YMP-QP-08.1,R 7	Pgs. 51-53				SAT	SAT	SAT
SUPP III	AP-3.10Q, R2,ICN2,ECN1 AP-3.12Q, R0, ICN4 AP-SIII.1Q, R 1, ICN 1 AP-SIII.3Q,R1,ICN0,ECN1	Pgs. 54-58 Pgs. 59-60 Pgs. 61-72 Pgs. 73-77	DR (2) DIR-02-02	CDA #1 & 2		SAT SAT SAT SAT	UNSAT SAT UNSAT SAT	SAT
SUPP V	AP-SV.1Q, R0, ICN 2 LANL-YMP-QP-S5.01, R0	Pgs. 78-81 Pg. 82	DR (1)			SAT SAT	UNSAT SAT	SAT
APP C	Expert Elicitation Purchasing	NA Pg. 32				SAT SAT	NI NI	SAT
TOTAL	PAGES = 82	-	2 DRs/1 DIR	3 CDAs	0 RECs	SATISFAC	TORY	

LEGEND: CDA

NI

Corrected During the Audit Not Implemented Deficiency Identification and Referral Deficiency Report DR(1) = BSC-02-D-034DIR

DR(2) = BSC-02-D-035DR REC Recommendation Satisfactory SAT UNSAT Unsatisfactory

ATTACHMENT 3

ACRONYMS / ABBREVIATIONS

AP Administrative Procedure

BSC Bechtel SAIC Company, LLC

CDA Corrected During the Audit

DCAR Document Control Action Request
DIR Deficiency Identification and Referral

DOE Department of Energy DR Deficiency Report

LANL Los Alamos National Laboratory

M&TE Measuring and Test Equipment

NI Not Implemented

NQS Navarro Quality Services

OCRWM Office of Civilian Radioactive Waste Management

OQA Office of Quality Assurance

QA Quality Assurance

QARD Quality Assurance Requirements and Description

QP Quality Procedures

REC Recommendations

RPC Records Processing Center

SAT Satisfactory

SN Scientific Notebook

UNSAT Unsatisfactory